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|-------------------------------|--------------------------|------------------|
| <b>Notice of Allowability</b> | Application No.          | Applicant(s)     |
|                               | 09/943,722               | PAVLAKIS ET AL.  |
|                               | Examiner<br>Jeffrey Siew | Art Unit<br>1637 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 9/26/03.
2.  The allowed claim(s) is/are 46-49.
3.  The drawings filed on 07 March 2003 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\* c)  None of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a)  The translation of the foreign language provisional application has been received.
6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
  - (b)  including changes required by the proposed drawing correction filed 07 March 2003, which has been approved by the Examiner.
  - (c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

|   |   |
|---|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892)   | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.            |
| <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | <input type="checkbox"/> Examiner's Amendment/Comment                             |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|   | <input type="checkbox"/> Other  |

### **REASONS FOR ALLOWANCE**

1. The following is an examiner's statement of reasons for allowance: Concerning claims 46-48 there is no prior art that teach a synthetic gene encoding a HIV-1 gag or HIV-1 env protein wherein at least one rarely used or less preferred codon in a natural gene encoding said protein has been replaced by a preferred codon encoding the same amino acid and wherein said rarely used or less preferred codon contains an inhibitory/instability region and said synthetic gene expresses protein at level higher than natural gene in in vitro mammalian system. Concerning claim 49 there is no prior art that teach or suggest a method of preparing a synthetic gene encoding a protein normally expressed by identifying rarely used and less preferred codons containing inhibitory/instability region in natural gene and replacing one or more said rarely used or less preferred codons with a preferred codon encoding same amino acid. The closest prior art is Clark (US4,959,455) who teach replacing rare codons with preferred codons but not in inhibitory/instability regions or in HIV.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **CONCLUSION**

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and

ALLOWED CLAIMS/ TJ

Claim 46 (currently amended): A synthetic gene encoding a HIV-1 gag or HIV-1 env protein normally expressed in an eukaryotic cell wherein at least one rarely-used or less preferred codon in a natural gene encoding said protein has been replaced by a preferred codon encoding the same amino acid, and wherein said rarely-used or less preferred codon contains an inhibitory/instability region, said synthetic gene expressing said protein at a level which is higher than that expressed by said natural gene in an in vitro mammalian cell culture system under identical conditions.

Claim 47 (previously presented): An expression vector comprising the synthetic gene of claim 46.

Claim 48 (previously presented): A mammalian cell comprising the synthetic gene of claim 47.

Claim 49 (previously presented): A method for preparing a synthetic gene encoding a protein normally expressed by mammalian cells, comprising identifying rarely-used and less-preferred codons containing an inhibitory/instability region in the natural gene encoding said protein and replacing one or more of said rarely-used or less-preferred codons with a preferred codon encoding the same amino acid as the replaced codon, so that a synthetic gene is prepared.

whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

  
JEFFREY SIEW  
PRIMARY EXAMINER

November 5, 2003